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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,275	03/28/2007	Ryozo Nagai	P30563	2170

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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
02/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
pto@gbpatent.com

Office Action Summary	Application No.	Applicant(s)	
	10/598,275	NAGAI ET AL.	
	Examiner	Art Unit	
	Charleswort Rae	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/2807*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's application and preliminary amendment, filed 3/28/07, are acknowledged.

Status of the Claims

Claims 1-20 are currently pending in this application and are the subject of this office action.

Priority

Receipt of a certified copy of the non-English foreign priority application, received 8/23/06, pursuant to 35 USC 119(a)-(d) is acknowledged.

Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-20 are rejected under 102(e) as being anticipated by Shidoji et al. (US Patent 2005/0250671).

Shidoji et al. (US Patent 2005/0250671) teach the exact polyprenyl acyclic compound recited in claims 6, 13, and 14 i.e. (2E,4E,6E,10E)-3,7,11,15-Tetramethyl-2,4,6,10,14-hexadecapentaenoic acid (Development Code: "NIK-333"); see para 0006). The acyclic polyprenyl compounds encompassed by claims 1, 2, 3, 4, 5, 7, 8, 9, 10, 11,

12, 15, 16, 17, 18, 19, and 20. Shidoji et al. also teach other examples of polyprenyl compounds, including conjugated polyprenylcarboxylic acids (polyprenoic acids) such as 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid and esters thereof (para 0016). Instant claim 5, 11, and 12 recite the compound 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid as taught by Shidoji et al. (para 0016). Claims 1, 2, 3, 4, 7, 9, 10, 15, 16, 17, 18, and 19 recite the term "acyclic polyprenyl compound as the active ingredient" or the term "the acyclic polyprenyl compound is a polyprenylcarboxylic acid," which read on the compounds taught by Shidoji et al. (para 0006 and para 0016). The term "a pharmaceutical composition containing a pharmaceutically acceptable additive for formulations together with an acyclic polyprenyl compound as an active ingredient" as recited in claims 7, 16, 17,18, and 19 and the term "a pharmaceutical composition for oral administration" as recited in claims 8 and 20 are reasonably construed to be satisfied by the teaching of Shidoji et al. of medicaments suitable for oral administration, wherein the desired pharmaceutical compositions can be prepared by using, as pharmaceutical carriers, excipients such as lactose, glucose, corn starch, and sucrose, disintegrants such as carboxymethylcellulose calcium, and hydroxypropylcellulose, lubricants such as calcium stearate, magnesium stearate, talc, polyethylene glycol, and hydrogenated oil, binders such as hydroxypropylcellulose, hydroxypropylmethylcellulose, carboxymethylcellulose, polyvinyl alcohol, gelatin, and gum arabic, moistening agents such as glycerine and ethylene glycol, as well as surfactants, flavoring agents and the like as optionally required (para 0019). The term "[a] medicament having an inhibitory action against

activation of a transcription factor KLF5" as recited in claim 1 overlaps with the teaching of Shidoji et al. of medicaments comprising polyprennyl compounds that activate PPAR, including PPAR alpha, or PPAR gamma as preferred targets (para 0021). Furthermore, the term "an inhibitory action against activation of a transcription factor KLF5" as recited in claim 1, the term "an inhibitory action against vascular remodeling," and the term "an inhibitory action against arteriosclerosis" are reasonably construed to be inherent characteristics of acyclic polyprenyl compounds. It is noted that no patentable weight is being given to these intended use limitations recited in claims 1-3, as the instant claims are directed to a composition.

For the above reasons, claims 1-20 are found to be anticipated by the cited prior ar

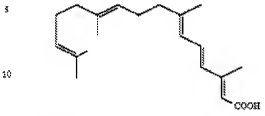
Claim rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-20 are rejected under 35 USC 102(b) as being anticipated by Muto (US Patent 5,820,057).

Muto (US Patent 5,820,057) teach the below compound, 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid, is an acyclic retinoid (polyprenoic acid) compound and is preferentially contained as a major component in the anticarcinogenic pharmaceutical composition in the form of a crystalline powder (col. 2, lines 2-15):



or a salt thereof and a pharmaceutically acceptable carrier.

3,7,11,15-Tetramethyl-2,4,6,10,14-hexadecapentaenoic acid is an acyclic retinoid (polyprenoic acid) and is preferably contained as a major component (at least 50 wt %, preferably, at least 90 wt %) in the anticarcinogenic pharmaceutical composition of the present invention. 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid is a crystalline powder with a white to lemon yellow color and is odorless. This compound functions to effectively prevent the recurrence of hepatocellular carcinoma (the occurrence of a second primary tumor), occurrence of hepatocellular carcinoma in high risk groups with chronic hepatitis and liver cirrhosis, and occurrence of cervical carcinoma intraepithelials, lung adenocarcinoma, lung squamous cell carcinoma, mammary tumors, and the like, in cell lines of the carcinoma. The compound also has relatively low toxicity.

Any pharmaceutically acceptable salt of 3,7,11,15-tetramethyl-2,4,6,10,14-hexadecapentaenoic acid may also be used.

Reference claim 6 is directed to a method of treatment comprising administering said compound orally or by injection; capsule comprising 150 mg of said active drug is specifically taught by Muto (col. 2, line 65 to col. 3, line 67, especially col. 3, lines 6-9). Claims 7, and 15-19, for example, recite the term "pharmaceutically acceptable additive" which is construed to be a necessary requisite for the preparation of a capsule as taught by Muto (col. 3, lines 6-9). No patentable weight is being given to the intended use limitations recited in the instant claims as these claims are directed to a composition. Furthermore, the term "an inhibitory action against activation of a transcription factor KLF5" as recited in claim 1, the term "an inhibitory action against vascular remodeling"

as recited in claim 2, and the term "an inhibitory action against arteriosclerosis" as recited in claim are reasonably construed to be inherent characteristics of the claimed composition.

For the above reasons claims 1-20 are deemed to be anticipated by the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

9 February 2008
CER

/Brian-Yong S Kwon/
Primary Examiner, Art Unit 1614